ERCC Workshop Summary and Next Steps

December 2, 2003

Gaithersburg MD

Workshop Goals

- ✓ 1. Move forward cooperatively and thoughtfully.
- ✓ 2. Stay focused, keep single purpose in mind.
- ✓ 3. Achieve consensus on the proposed specifications & design plan.
- ✓ 4. Make/renew your commitment to collaboratively producing quality materials and test data.
- ✓ 5. Keep talks & discussion within scheduled time.

Issues to Address and Resolve

- Specificity assurance, limitation clearly defined
- Promoter T3 (vs.T7)& first 10 bases standardized, using different promoter than is used in most amp kits as added assurance, commercial use of the vector free of stipulations
- Well-defined analytical approach, methods and assumptions for testing and comparability studies
- Test in N number and types of complex backgrounds
- Precisely define performance metrics and assumptions
- Distribution criteria: Limitations/maximums
- Clarification& guidance on IP issues on clones and vectors
- Clone availability vs individual synthetic RNAs available, clones only for production not as a product per se. Clones deposited with ATCC.

Next Steps

- Post meeting slides & summary
- Solicit feedback & discussion via NIST website
- Canvas community regarding dynamic range for sensitivity (RT-PCR, microarrays)
- Invite wider participation
- Applications section in the document – intended use
- Road map milestones vs. nice to haves
- Clearly lay out rules of engagement: “Value received for value given,”
  - Assumptions/disclosure of all pertinent experimental information
- Open source S/W to evaluate results-working group?
- Proposal to NCCLS for protocol work
- Follow up with M Holden/NIST re. RTPCR standard
- Consider looking for funding opportunities (timing issues)
- Bob S suggest vectors
- Finish first set of clones

THANK YOU!